Johns Hopkins Faults Researcher in Human Drug Trial

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A Johns Hopkins University researcher testing a cancer drug in India violated safety procedures, a university investigation has concluded.

As a result, the researcher has been barred from leading any medical studies involving human subjects in the future, officials announced yesterday in releasing the results of its investigation.

No one is known to have been harmed by the experiment, but it was conducted without the school's knowledge or permission and violated both school policies and federal requirements, school officials said. In addition, the university had been lax in not launching an investigation before reports of irregularities appeared in the Indian media, the report found.

"The whole study was not up to the standard of Johns Hopkins University -- it fell far short," said Richard E. McCarty, dean of the university's Zanvyl Krieger School of Arts and Sciences.

The researcher failed to get approval from a university panel that must approve all research to ensure that it is safe, failed to get Food and Drug Administration approval to export the drug being tested, and had insufficiently tested the drug's safety by only experimenting in mice before trying it on people, McCarty and other officials said.

McCarty said that the school had not launched an investigation earlier because officials did not know the trial was underway.

The trial, which involved more than two dozen oral cancer patients, was intended to establish the safety of a medicine called tetramethyl NDGA.

The university did not name the researcher, but biologist Ru Chih Huang had acknowledged previously that she was the scientist involved. In a telephone interview last night, Huang defended her study and conduct and questioned the university's decision to punish her.

Huang said she had believed that only medical school researchers had to get approval from the university's Institutional Review Board to conduct a trial. As a scientist who was not directly in charge of patient care, she thought that approval from Indian authorities would suffice. She also said the university had been aware of the trial from the start and had even written two checks funding the trial -- one of which was sent to India the month before the trial began.

"It's authorized by the dean's office," she said. "He knew this before the trial started."

In an earlier interview, Huang said that the experimental medicine had been thoroughly tested in dogs, rats, rabbits and mice before the human trial.

A report by the Indian Medical Association in the state of Kerala, where the trial was conducted, said that

investigators had tracked down eight volunteers in the trial, none of whom had suffered adverse effects. The Indian doctors said that although some procedures had not been followed, there was no evidence that patients had been exploited, misled or placed at undue risk.

A statement by India's government in September said that contrary to early reports, the drug used in the trial had not been banned. Although there was no "violation of human rights," the statement said "a serious view" was being taken regarding certain regulatory and procedural lapses.

The university's report was also filed with two agencies at the Department of Health and Human Services, whose rules may have been violated: In addition to the FDA, the university also sent the report to the Office for Human Research Protections, which monitors patient safety in trials that use federal money.

A small amount of federal money might have been used in the trial, McCarty said. Huang said she had personally funded much of the trial by giving a gift to Johns Hopkins, which then wrote checks to the Indian institution running the trial. Johns Hopkins owns the patent on the experimental chemical, and both the university and Huang would benefit financially if the chemical was found to be effective and marketed.

Vera Hassner Sharav, president of the patient advocacy group Alliance for Human Research Protections, said the university report ignored the institution's own role in permitting the research. She called for an independent investigation. "Internal self-investigation and self-regulation does not work," she said. "The public trust will not be restored with this kind of self-serving finding."

Research at Johns Hopkins has been under heavy scrutiny since an asthma patient died during a drug trial in June. Federal regulators put all of the university's 2,200 trials on hold and ordered a review of each. University officials said yesterday that they had almost completed the reviews.